

09/101,723 08/13/98

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**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

 Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
WILLIAM H DIPPERT COWAN LIEBOWITZ & LATMAN 1133 AVENUE OF THE AMERICAS NEW YORK NY 10036-6799	08/13/98	LAYNO, C	

3737	EXAMINER
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ART UNIT	PAPER NUMBER
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DATE MAILED: 4/21/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

NOTICE OF ALLOWABILITY

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to PAPER NOS. 7 & 8 AND ATTORNEY INTERVIEW (4/14/00).

☒ The allowed claim(s) is/are 1-60.

☐ The drawings filed on 2/15/00 are acceptable.

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR REPLY to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 6.

☒ including changes required by the proposed drawing correction filed on 2/15/00, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this notice should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Notice of Draftperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

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DETAILED ACTION

1. Acknowledgment is made of applicant's amendment and 3-month extension of time which were received by the Office on February 15, 2000. These documents have been made of record in the file as Paper Nos.8 and 7, respectively.

Information Disclosure Statement

2. Acknowledgment is made of applicant's Information Disclosure Statement (PTO-1449) which was received by the Office on February 15, 2000. This document has been made of record in the file as part of Paper No.7.

Drawings

3. The corrected Fig.4B was received by the Office on February 15, 2000. This corrected drawing is approved by the Examiner.

4. In view of applicant's modifications to Fig.4B to show implantable light sources and waveguides, the Examiner is withdrawing the 37 CFR 1.83(a) objection against the drawings which was made in the last Office Action.

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Specification

5. In view of the applicant's submission of an Abstract and corrections to the specification, the Examiner is withdrawing the objections which were made against the specification in the last Office action.

Claim Objections

6. In view of applicant's numerous modifications to the claims, the Examiner is withdrawing the objections which were made against claims 11, 13-15, and 43-45 in the last Office action.

Claim Rejections - 35 USC § 112

7. Upon further reconsideration of applicant's recitation of support in the specification for the features of a "light source" having a specific frequency range and a "means of irradiating", the Examiner is withdrawing the 35 U.S.C 112 1st paragraph rejection which was made in the previous Office action.

8. In view of applicant's many modifications to the claims, the Examiner is withdrawing the 35 U.S.C 112 2nd paragraph rejections which were made against claims 1-26, 28-45, 47-51, and 58 in the last Office action.

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Claim Rejections - 35 USC § 102

9. In view of the defective filing dates of the Kieval references, the Examiner is withdrawing the 35 U.S.C 102(e) rejections of Kieval '464 and Kieval '079 which were made against claims 1, 2, 4, 7-9, 11, 12, 14, 15, 18-23, 26, 27, 30, 32, 35-37, 39-42, 44, 45, 49, and 51 in the last Office action. See the attached Interview Summary (PTO-413).
10. Claims 1-60 are now deemed to be allowable over the prior art of record for the reasons given below in the Examiner's statement of reasons for allowance.
11. The application has been amended as follows:
- p.30, lines 29-34, replace the description of Figs.9-23 with the following descriptions

" Fig.9 shows experimental results of a 10mA constant current pulse having a duration of 20 msec and delayed 5 msec after heart pacing.

Fig.10 shows experimental results of a 5mA constant current pulse having a duration of 80 msec and delayed 2 msec after heart pacing.

Fig.11 shows experimental results of a 5mA constant current pulse having a duration of 20 msec and delayed 2 msec after heart pacing.

Fig.12 are a series of graphs from experiments resulting in significant increases in aortic flow and pressure.

Fig.13 show results from repeating the experiment of Fig.12 but using electrodes for control.

Fig.14 shows experimental results from pacing the right atrium at 3 Hz.

Fig.15 shows results of repeating the experiment of Fig.14 but with four controlling electrodes instead of two.

Fig.16 shows results from a repeat of the experiment of Fig.14 but in which no sensing electrode is used.

Fig.17 shows results from a repeat of the experiment of Fig.14 but in which no pacing electrodes are used.

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Fig.18A is a series of graphs showing results from an experiment in which a heart was made ischemic.

Fig.18B is a series of graphs showing results from an experiment in which the output of the heart was reduced.

Fig.19 shows results from an experiment involving pacing the left ventricle of a rabbit.

Fig.20 shows results of the same experiment as in Fig.19 but using outputs from an ultrasonic flowmeter.

Fig.21 shows the results of an experiment in an in-vivo heart in which the heart was not paced.

Fig.22 shows results of an experiment similar to that of Fig.21 which shows an increase of about 11% in the aortic flow.

Fig.23 shows results of an experiment similar to that of Fig.21 which shows an increase of about 11% in the aortic flow."

-Change the title to:

"CONTROLLING HEART PERFORMANCE USING A NON-EXCITATORY ELECTRIC FIELD"

Reasons for Allowance

12. The following is an examiner's statement of reasons for allowance:

Claims 1, 18, 19, and 30 describe methods and means, respectively, of therapeutically modifying heart activity by applying a non-excitatory electric field at a time when it is unable to generate a propagating action potential. Although the Kieval '079 and '464 patents describe devices which perform similarly, these references could not be used due to their defective filing dates (see attached Interview Summary). Unable to find any other references which show or teach all of applicant's claimed method steps and corresponding hardware, the Examiner deems claims 1, 18, 19, 30, and their depending claims to be allowable over the prior art of record.

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Claims 16, 17, 46, and 47, as amended, recite method steps wherein the non-excitatory pulses are used for inhibiting the propagation of action potentials across the heart during surgery. Since none of the prior art references of record show or teach applying cardiac stimulation pulses for this purpose, the Examiner deems these claims to be allowable.

Claims 24 and 25, as amended, recite method steps used in modifying heart activation behavior in order to counteract arrhythmias including the inventive step of “changing the refractory period” of a heart segment (claim 24) and “reversibly blocking” the activation of a heart segment to obtain a “desired change” in the activation profile of a portion of the heart. Unable to find these features in the prior art, the Examiner also deems these claims to be allowable.

Claims 52 and 55 recite a method and corresponding apparatus for modifying activity of the heart including “providing one implantable light source” for generating therapeutic pulses of light. The Examiner could find no implantable defibrillators or pacers having a “light source” for providing therapy pulses to a patient.

Claims 53 and 56 describe a method and corresponding apparatus for modifying the activity of a heart as in claims 52 and 55 above, but substituting a “means for irradiating” using RF frequency radiation for “light source” to treat the patient. Again, since the Examiner could find no means of this type for generating radiation signals meeting applicant’s claimed frequency of pulses, these claims are deemed to be allowable.

Claims 54 and 57 describe a method and corresponding apparatus for applying a non-excitatory electric field to both a first and a second chamber of the heart to force the chambers to

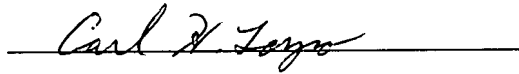
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contract. The applicant's claims state that the force of contraction is stronger in the second chamber than in the first. The Examiner could find no prior art relating the use of "non-excitatory" electric fields in this manner; as a result, these claims are also deemed to be allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694.


Carl H. Layno
Patent Examiner, Art 3737

CHL
April 20, 2000

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

QM32/0421

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NEW YORK NY 10036-6799

APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/101,723	08/13/98	060	LAYNO, C	3737 04/21/00
First Named Applicant	DARVISH, 35 USC 154(b) term ext. = 0 Days.			

TITLE OF INVENTION: CONTROLLING HEART PERFORMANCE USING A NON-EXCITATORY ELECTRIC FIELD

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
2	20066-05	607-009.000	L44 UTILITY	YES	\$605.00	07/21/00

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.

Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

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